

Message

From: D'Amico, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78A91F83C4414910BE286EFE02004DBC-D'AMICO, LOUIS J.]
Sent: 1/21/2017 8:17:36 PM
To: Jones, Samantha [Jones.Samantha@epa.gov]
Subject: RE: FYI - Inside EPA on release of BaP assessment

Me too. have fun with all your roomies!

Louis D'Amico, Ph.D.
Assistant Center Director for Communications and Regulatory Support (Acting)
U.S. EPA, ORD/NCEA
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O: (703) 347-0344 M: Ex. 6 Personal Privacy (PP)

From: Jones, Samantha
Sent: Saturday, January 21, 2017 3:17 PM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: RE: FYI - Inside EPA on release of BaP assessment

Cool! I have a limited time to work before the ladies come back ☺

Hope you can relax and enjoy your Saturday...later!

Samantha J. Jones, Ph.D.
Associate Director for Science, ORD/NCEA
Phone: (703) 347-8580

From: D'Amico, Louis
Sent: Saturday, January 21, 2017 3:16 PM
To: Jones, Samantha <Jones.Samantha@epa.gov>
Subject: RE: FYI - Inside EPA on release of BaP assessment

Yeah.... I hear you. I'm trying to knock a couple things out before chilling out for the rest of the day.

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From: Jones, Samantha
Sent: Saturday, January 21, 2017 3:13 PM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: RE: FYI - Inside EPA on release of BaP assessment

Ha, yes, but I elected to stay home and work...dealing with chloroform first before I move on to manganese and the other 97 problems I got ☺

Samantha J. Jones, Ph.D
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Phone: (703) 347-8580

From: D'Amico, Louis
Sent: Saturday, January 21, 2017 3:12 PM
To: Jones, Samantha <jones.samantha@epa.gov>
Subject: RE: FYI - Inside EPA on release of BaP assessment

Shouldn't you be out marching?

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From: Jones, Samantha
Sent: Saturday, January 21, 2017 3:12 PM
To: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: RE: FYI - Inside EPA on release of BaP assessment

Working hard?

Samantha J. Jones, Ph.D
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From: D'Amico, Louis
Sent: Saturday, January 21, 2017 3:07 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <jones.samantha@epa.gov>
Subject: FYI - Inside EPA on release of BaP assessment

<https://insideepa.com/daily-news/latest-epa-chemical-assessment-shows-hurdles-novel-skin-risk-value>

Latest EPA Chemical Assessment Shows Hurdles For Novel Skin Risk Value

EPA's final Integrated Risk Information System (IRIS) assessment of benzo(a)pyrene (BaP) omits a first-time dermal cancer risk estimate that was included in draft versions of the assessment, and explains the methodology to start including such estimates remains under development but could be addressed later in a separate analysis. Prior to the 2013 and 2104 BaP draft assessments, EPA had never included a dermal risk value in an IRIS analysis, and the value quickly became the most scrutinized aspect of the documents. Several industry groups protested EPA's dermal cancer calculation, arguing that the estimate of 0.006 per micrograms per day (ug/day) was unrealistically strict and could lead to major, expensive changes in how the agency's Superfund office assesses cleanup sites and reaches decisions on remediation requirements. They urged EPA to create a methodology for crafting dermal risk values rather than trying to create an approach in the midst of an IRIS assessment. At a workshop last summer that IRIS hosted to try to gather ideas to improve the dermal risk value, EPA's chemical manager explained the agency's interest in creating such a risk estimate. Kathleen Newhouse, EPA's chemical manager for BaP, referenced EPA's risk assessment guidelines for Superfund site cleanups, which she said "note the lack of dermal

toxicity values may significantly underestimate" the risks polycyclic aromatic hydrocarbons (PAHs) in soil pose. BaP is one of the better-known PAHs.

EPA's Science Advisory Board (SAB) panel, which met in the spring of 2015 to begin peer reviewing the draft document, did not necessarily consider the conclusion overly strict. One of the panelists, American Cancer Society Managing Director Kenneth Portier, noted that skin cancer is extremely common, and that removals of small malignant patches of skin are generally not reported to cancer registries. As a result, Portier suggested, EPA's draft BaP potency estimate may not be overly large.

Still, science advisors struggled with the recommendations on how to best calculate the dermal cancer risk, noting both its novelty and scientific uncertainties in various approaches. The final report, released last April, suggests that there are multiple dose-metric approaches for beginning to estimate the dose, and little information to guide which method EPA should choose.

Following SAB's recommendations, the IRIS program hosted the workshop in June 2016 to discuss the approach and how they might strengthen it.

Index Chemical

But these efforts apparently came to naught. The final assessment does not contain a dermal risk value. "A quantitative estimate of skin cancer risk from dermal exposure is not included in this assessment, as methodology for interspecies extrapolation of dermal toxicokinetics and carcinogenicity are still under development," the document explains.

In a response to the SAB's review, released Jan. 19 with the new assessment, EPA adds that staff "is reviewing the SAB panel's specific advice and is initiating further scientific discussions to gather a broad range of scientific perspectives in order to further refine EPA's approach for deriving a [BaP] dermal slope factor. In the interest of timeliness and in consideration of the support for the cancer characterization and the other toxicity values within the [BaP] assessment, the continuing efforts to refine the dermal slope factor methodology will be addressed in a separate assessment." EPA's assessment of BaP is important not just because the compound is a common environmental contaminant but also because EPA has proposed using it as the index chemical in a relative potency factor approach for PAHs. The chemicals are carcinogenic and stem from a wide range of natural and industrial sources, including crude oil, asphalt and vehicle emissions.

The assessment follows the 2010 peer review of an EPA approach to assess the risks of multiple PAHs. EPA proposed using BaP as a reference chemical, similar to a common approach for risk analyses of dioxin mixtures. The peer reviewers urged EPA in the long term to adopt a whole mixtures approach to assessing PAHs' risks, but called on the agency in the interim to update the BaP IRIS assessment before implementing the reference chemical approach. They argued that the earlier IRIS assessment that was the basis for the approach was outdated.

The IRIS assessment does not appear to address the reference chemical approach, which was questioned during the interagency review process. A second interagency review, conducted last fall, and the last step before EPA finalizes an IRIS assessment, included comments from NASA questioning EPA's decision to consider BaP as an 'index chemical' for the entire group of [PAHs]. EPA does not provide a documented, sound case for this choice. NASA notes that BaP, with its very conservative approach, results in a potentially over restrictive approach to address the large number of PAHs in the environment without a defensible justification. NASA requests EPA reconsider this approach and target BaP as one chemical," that agency's Dec. 15 comments state.

Human Carcinogen

EPA, in a January 2017 response to comments replied, "This assessment is the IRIS toxicological review of BaP as one chemical. Regarding using BaP as an index chemical for assessing the carcinogenicity of PAHs, justification of suitable index chemicals is more pertinent in PAH assessment support documents."

The 1984 IRIS assessment that is posted on the IRIS website as an archived document characterizes BaP as a probable human carcinogen, and set a cancer slope factor, or estimate of oral cancer potency, of 11.53 per milligram per kilogram body weight per day (mg/kg-day)⁻¹. Similarly, the document included an inhalation risk factor, of 6.11 (mg/kg-day)⁻¹. The new assessment upgrades BaP to a human carcinogen, and determines that it is mutagenic, resulting in its use of the age-dependent adjustment factor, intended to make assessments more protective of children in assessments of chemicals to which they are expected to be more susceptible.

EPA calculates a weaker cancer slope factor, or estimate of cancer potency when ingested, than before of 1 per mg/kg-day. The agency also provides an inhalation unit risk, or an estimate of cancer potency when inhaled, of 6x10⁻⁴ per microgram per cubic meter of air (ug/m³).

The document includes first-time non-cancer risk values, a reference dose (RfD), or the maximum amount EPA estimates can be ingested daily over a lifetime without anticipating an associated non-cancer health effect, and the reference

concentration (RfC). The RfC is analogous to the RfD by inhalation exposure. The 1984 assessment did not include non-cancer risk values.

EPA sets the final RfD at 3×10^{-4} milligrams per kilogram bodyweight per day, based on data indicating developmental toxicity. The final RfC is 2×10^{-6} milligrams per cubic meter of air, also based on developmental toxicity. These values did not change from those EPA proposed in its 2014 draft. -- *Maria Hegstad* (mhegstad@iwpnews.com)

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